November 10, 1998

President's Council on Food Safety

Public Comment

(35)

My name is Paula J. Copalello,

I am speaking on behalf of those affected with latex allergy and those who are unaware that latex allergy is a problem in food handling.

One of the issues concerning food safety is the problem of latex gloves contaminating food. The idea that latex gloves could contaminate food seems strong but a serious and new disease has developed as a result of latex gloves. The disease is latex allergy which causes a range of symptoms from hayfever type symptoms to asthma to anaphylactic shock and death Latex allergy is prevalent in many groups of individuals. Patients with spina bifida and congenitourinary abnormalities have a prevalence of latex sensitization of 1 8-73%. In health care workers it is 3-17%. Atopic patients 6.8%. In patients who have undergone multiple procedures it is 6.5% (Sussman, 1996) and findings now show that 1-6% of the general population may be affected with latex allergy.

For those who are not familiar with latex, I am referring to Natural Rubber Latex (NRL). This is a substance obtained from the rubber tree to make products like latex gloves. There are many allergy producing proteins in latex products that are manufactured with latex. These proteins are shed from the surface of the gloves and cause the allergy in the person that wears the gloves. However, the important point that we are here to make today is the fact that the allergy producing proteins in latex gloves transfer onto foods, dishes and other surfaces and can produce life threatening allergic reactions in persons with latex allergy who consume those foods. The transfer of allergenic proteins from latex gloves to foods is well documented in laboratory research

and the resulting severe allergic reactions among people who consume these foods is documented in clinical reports.

We know that food handlers are wearing gloves to prevent contamination of food with harmful organisms but they are unaware of the hazards of wearing latex gloves to themselves and the persons eating the foods.

The National Institute of Occupational Safety and Health (NIOSH) has recommended that latex gloves should not be worn by food handlers. This is the position of the American Nurses Association (ANA), the Illinois Nurses Association (INA), the American Academy of Allergy, Asthma and Lmmunology (AAAAI), the American College of Allergy, Asthma and Immunology (ACAAI) and the National Institute of Occupational Safety and Health (NIOSH).

In the interest of the safety of latex allergic children and adults with latex allergy and for the sake of preventing reactions to those who could suffer potentially life-threatening reactions from food prepared by workers wearing latex gloves, we are requesting you to take action and follow the recommendations of the National Institute of Occupational Safety and Health (NIOSH) to stop the use of latex gloves among food handlers.

**Thank you,**

Paula J. Copalello, RN

Reference

Sussman, Gordon, M.D., Gold, Milton, M.D. Guidelines *for the Management of Latex* Allergies and *Safe Latex Use in Health Care* Facilities. March 1996, p. 6.

# AAAAI and ACAAI joint Statement Concerning the Use of Powdered and Non-powdered Natural Rubber Latex Gloves

*This statement was developed by a joint subcommittee of the American College of Allergy, Asthma and Immunology (ACAAI) and the American Academy of Allergy, Asthma and Immunology (AAA&I). It was approved by the ACAAI Board Of Regents on the recommendation of the Executive Committee On July 21, 1997.*

IgE-mediated latex allergy is the result of chc exposure of susceptible individuals to latex rubber proteins. Medical &vices – principally latex gloves' – are the largest single source of exposure to these pocenr allergens. Exposure to bioavailable allergen may be by direct contact with an offending device" or by inhalation of allergen carried by comstatch powder with which most nowdered gloves arc coated.[1-3] The clinical manifestations of latex allergy range from mild contact urticaria co fatal anaphylaxis.

Allergisensitization to constituent latex rubber proteins is linkc to exposure to latex allergens in the vast majority of cases. Direct exposure co latex allergens results from either contact exposures to medical devices and latex gloves[4-1] or from respiratory exposure to latex aeroallergen carried by donning glove powders.[4-3]

Latex occupational asthma may result from inhalation of latex rubber proteins carried on glove powder from latex gloves.[6-4] Asthma caused by occupational exposure may continue and lead to persistent impairment, and rarely, to disability.[7]

These risks – of acute allergic reactions and of occupational asthma – can be reduced only by curtailing exposure co latex rubber proteins.[10,11] Wc recommend that the following steps, which utilize currently available devices, be taken to reduce these risks:

- Latex gloves should be used only as mandated by accepted Universal Precautions standards. The routine use of latex gloves by food handlers, housekeeping, transport and medical personnel in low risk situations (e.g. food handling, bed transport, routine physical examination) should be discouraged,
- Only low-allergen latex gloves should be purchased and used. This will reduce the occurrence of reactions among sensitized personnel and should reduce the rate of sensitization.[12-14]
- **Only powder-fret latex gloves** should be purchased and used. This will reduce latex rubber aeroallergen levels and exposure.[15-17]

ACAAI American College of Allergy, Asthma & Immunology

## References


1. Slater J. Latex Allergy. J Allergy Clin Immunol 1994;94:139-49.
2. Charous 8. Hamilton R, Yunginger J. Occupational latex exposure: characteristics of contact and systemic reactions in 47 workers. J Allergy Clin Immunol 1994;94(1):12-18.
3. Sussman G, Beezhold D. Allergy co latex rubber. Am Int Med 1995;122(1):43-46.
4. Beezhold D, Beck W. Surgical glove powders bid latex antigens. Archives of Surgery 1992;127: 1X4-57.
5. Tomazic V, Shampaine E, Lamanna A, et al. Cornstarch powder on latex products is an allergen carrier. J Allergy Clin Immunol 1994;93(4):751-8.
6. Swanson M, Bubak M, Hunt L, et al. Quantification of occupational latex aeroallergens in 3 medical center. J Allergy Clin Immunol 1994;94:445-551.
1. Swanson M, Yunginger J, Reed C. Immunochemical quantification of airborne natural tubber allergens in medical and dental office buildings. In: Maroni M, cd. Ventilation and indoor air quality in hospitals. 1996:257-62.
8. Heilman D, Jones R, Swanson M, cc al. A prospective, controlled study showing that rubber gloves are the major contributor to latex aeroallergen levels in the operating room. J Allerg Clin Immunol 1996;98:325-30.
9. Paggiaro P, Vagaggini B, Bacci E, et al. Prognosis of occupational asthma. Euc Respir J 1994;7:761-67.
10. Charous B, Banov C, Bardana EJ, cc al. Latex allergy – an emerging healthcare ptobkm. Ann Allergy Asthma Immunol 1995;75:19-21.
11. Kelly K, Sussman G, Fink J. Stop the sensitization. J Allerg Clin Immunol 1996;98:857-858.
12. Jones R, Scheppmann D, Heilman D, cc al. Prospective study of extractable latex allergen contents of disposable medical gloves. AM Allergy 1994;73(4):321-25.
13. Patterson P. Allergy issues complicate buying decisions fat gloves. OR Manager 1995;1 l(6).
14. Yunginger J, Jones R. Fransway A, et al. Extractable latex allergens and proteins in disposable medical gloves and other rubber products. J Allergy Clin Immunol 1994;93:836-42.
15. Tarlo S, Sussman G, Contala A, et al. Control of airborne latex by USC of powder-free gloves. J Allergy Clin Immunol 1994;93:985-9.
16. Vandenplas 0, Delwiche J-P. Depelchin S, et al. Latex gloves with a lower peotein content reduce bronchial reactions in subjects with occupational asthma caused by latex. Am J Respir Crit Care Med 1995;151:887-891.
17. Siu S, Smith G, Sussman G, et al. Reduction of airborne latex protein exposure by use of low protein, powder-free gloves. J Allerg Clin Immunol 1996;97:325.


8.5 W. Algonquin Road, Suite 550 @Arlington Heights, IL 60005 . Phone (847) 427- 1200 • Fax (847) 427-1294

## Preventing Latex Allergy

**Q.** How can *latex allergy be* prevented?

A. All products and medical devices that come in contact with individuals al risk should bc reviewed for possible latex content. A label of "hypoallergenic" *does not* mean that a product is latex-free.

In general, only low allergen, preferably non-powdered latex gloves should be used. The powders that are used in some latex gloves can absorb latex proteins and carry them into the air where they may bc inhaled by latex-sensitive individuals.

**Q.** How can health *care workers who must wear* rubber *gloves* to protect *themselves from* transmissible disease protect *themselves* from developing *latex* hypersensitivity?

A. Health care workers with a history of latex sensitivity mun stop wearing latex gloves and their co-workers must not use powdered gloves. Care should be exercised in the choice of substitutes, since all synthetic or non-latex products arc not equally impermeable io blood-borne pathogens.

Health care workers with a history of glove-associated skin irritations, or contact dermatitis, should usc alternative gloves (which may include latex gloves) and lopical treatments io relieve. their *symproms.* Some petroleum-based products have been shown lo compromise the barrier function of latex gloves, and care should be taken in the choice of treatments used to relieve contact dermatitis.

**Q.** *What e/se can be done to protect against latex allergy?*

A. *The* FDA in June 1666 proposed mandatory labeling of latex rubber in medical devices and banning of the term "hypoallcrgcnic" on latex-containing medical devices, requirements that have been urged by the American College of Allergy. Asthma & Immunology. The College also has proposed that the FDA and other government agencies:

establish maximum levels of extractable latex allergen in gloves

- "fast track" Ihc approval process of diagnostic tests for latex allergy
- conduct or fund epidemiologic studies lo identify causes of latex allergy and minimize risk factors
- address issues of patient-worker safely in Ihc medical selling
- consider content labeling for consumer products that contain lalcx rubber

## Diagnosis and Treatment

**Q.** How *is a* suspected later *allergy confirmed?*

A. *A* skin prick test may be done to test for lalcx allergy, but there arc currently no licensed reagents commercially available for the lest. Because of the potential for a life-threatening anaphylaclic reaction to the test itself, skin prick tests for latex allergy should be performed only under the close supervision of an allergy spccialisl. An allcrgisl-immunologist also can perform a blood test to confirm Ihc presence of IgE anti-latex antibodies. Skin patch tests arc used io evaluate the cause of skin irritations, or contact dermatitis, caused by rubber gloves.

**Q.** *How are later allergies treated?*

A. There arc a number of medications available lo treat the symptoms of latex allergy once it develops. However, because there is no cure yet, the best "treatment" is prevention. An allergy specialist can provide more informalion on how lo manage allergic reactions lo latex.


A.L.E.R.T., Inc.

ALLERGY TO LATEX EDUCATION A RESOURCE TEAM INC.

Providing latex allergy education and support services

Phone (414)677-9707
(888)97-ALERT
Fax (414)677-2808

P.O. Box 23722
Milwaukee, WI 53223

ACAAI American College of Allergy, Asthma & Immunology

85 West Algonquin Road, Suite 550, Arlington Heights, Illinois 60005
(847) 427-1200 • Fax (847) 427-1294


# Q&A: Latex Allergies

*The incidence of serious allergic reactions to latex has increased drama tically in recent years. In rare cases, these allergies can be* ***fatal.*** *Health care workers and others who are frequently exposed to products containing latex should be aware of the potential for developing an allergic reaction, and individuals who exhibit symptoms of the allergy should be alerted to the need to avoid future exposure to latex products.*

## About Latex Allergy

**Q.** *What is latex allergy?*

A. *Latex* allergy, or hypersensitivity, occurs when the body's immune system reacts to proteins found in natural rubber latex. The immune system launches a "defense" that can cause a host of unpleasant and, in some cases, life-threatening symptoms. It is the same type of generalized allergic reaction seen when individuals who are allergic io bee venom receive a bee sling.

**Q.** *What triggers the immune system's reaction to latex?*

A. Some individuals have specific antibodies. called IgE antibodies, that make them hypersensitive to the proteins in natural rubber latex. IgE-mediated reactions to latex proteins are responsible for most and for the most severe allergic reactions lo latex. Also, various chemicals that are added to latex during processing may be responsible for some local skin reactions, but these additives have not been implicated in the more generalitcd. potentially fatal allergic reactions associated with latex.

## About Natural Rubber Latex

**Q.** *What is natural rubber latex?*

**A.** Natural rubber latex is a processed plant product derived almost exclusively from the tree *hevea braziliensis* found in Africa and Southeast Asia. Natural rubber latex should not be confused with butyl- or petroleum-based synthetic rubbers. Synthetic products, including latex house paints, have not been shown to pose any hazard to latex-sensitive individuals.

**Q.** *What products contain latex?*

**A.** Latex is a common component of many medical supplies, including disposable gloves, airway and intravenous tubing, syringes, stethoscopes, catheters, dressings and bandages. Many of these medical devices come into contact with mucous membranes, which enhances the absorption of latex proteins that can trigger an allergic reaction. Latex gloves also frequently are implicated in allergic reactions due to the repeated direct exposure of the wearer's hands lo latex proteins or due to airborne latex proteins that are absorbed by powders used to line some latex gloves.

While latex also is found in as many as 40.000 consumer products, including condoms, balloons, athletic shoe soles, tins, underwear leg and waisl bands, rubber toys, nipples and pacifiers, these rarely cause problems except io the most sensitive patients.

## Symptoms of Latex Allergy

**Q.** *Whar are the symptoms of latex allergy?*

**A.** Allergy to latex proteins is a new medical problem with symptoms similar ıo those seen in individuals who are allergic 10 bee venom or cat dander. Reactions on exposure to the allergen are generally acute and may mimic hay fever or asthma, with symptoms such as nasal congestion, hives or difficulty breathing. The most severe cases can result in anaphylaxis. a potentially fatal reaction that affects many parts of Ihc hody al once. Symptoms arc usually immcdiatc. progress rapidly and may include a dangerous drop in blood pressure, flushed skin.



difftculty hrcathing, swelling of the throat, tongue and nose, and loss of consciotrsness. Emergency medical attention should be sought at thc first sign of an anaphylactic reaction.

Skin problems resulting from the use of lalcx and non-latex gloves are frequently confused with latex allergy. Contact dermatitis is a frequent problem in glove wearers which can be due to an irritant contacl dermatitis caused by frequent hand-washing and drying with irritating soaps, skin abrasions from donning and removing gloves and maceration of skin covered by an impermeable barrier. It can also be due ıo a "chemical sensitivity" dermatitis caused by a contact allergy to one of the chemicals used in the production of rubber gloves. These local skin problems are virtually never a result of true lalcx allergy.

**Q.** How *do the symptoms develop?*

**A.** In most cases, latex allergy develops after repeated exposures to latex. It should be noted, howcvcr. that direct physical contacl with latex-containing products is not needed to trigger the allergic reaction. Cases of anaphylaxis have resulted from inheling latex proteins, which can be absorbed by the powder that is used to line some latex gloves. When the gloves are snapped on and off, the proteins become airborne and can pose a risk to some individuals with latex hypersensitivity.

## Prevalence of Latex Allergy

**Q.** How *common is latex allergy?*

**A.** It is difficult to say how widespread the problem of latex allergy may be. Approximately 1.000 cases of allergic or anaphylactic reactions to latex-containing medical products have been reported ıo the U.S. Food and Drug Administration (FDA) since 1988. It is assumed that many other cases go unrcportcd. In onc 1994 study, 6 pcrccnl of vdluntccr blood donors were found to have increased levels of anti-latex IgE antibodies, although many of the volunteers did not show symploms of lalcx allergy. Other research suggests that morc than 100,000 health care workers may be at risk for developing latex allergy.



**Q.** *Why is the incidence of latex allergy increasing?*

**A.** The introduction of universal precautions in health care settings including the widespread use of lalex gloves ıo prevent the spread of AIDS and hepatitis B is believed ıo be the primary cause of lhe increased prevalence of latex allergy. Also, there is greater awareness and repotting of latex allergy lhan in the past.

## Individuals at Risk

**Q.** *Who is at greatest risk for latex allergy?*

**A.** *The greatest* risk is to individuals who are repeatedly exposed to products containing latex, particularly:

Patients with a history of early and/or recurrent surgical or medical procedures, such as children with spinal bifida.

Health care personnel and others who wear latex gloves.

Individuals with occupational exposure, such as workers involved in the manufacture of lalex gloves or catheters.

Other risk factors are less defined but appear to include:

A history of hay fever or other allergic problems.

A history of food allergies lo tropical fruits, hazelnuts, chestnuts or stone fruits, particularly if progressive in scope or severity.

Hand dermatitis that is severe or has changed in severity in an individual who wears latex gloves.

**Q.** *Who is most at risk of developing a life-threatening anaphylactic reaction IO latex?*

**A.** The risk of anaphylaxis appears to be greatest in individuals with prior allergic reactions to lalex-containing objects or prior, unexplained reactions or anaphylaxis during a medical or surgical procedure. Health care providers with a history of severe or worsening latex-glove-induced cczcma, hives or work-related rhinitis or asthma-like symploms should be especially cautious.